

Targin® Prolonged Release Tablet

Oxycodone hydrochloride / Naloxone hydrochloride (5mg/2.5mg, 10mg/5mg, 20mg/10mg, 40mg/20mg)

What is in this leaflet

1. What *Targin®* tablet is used for
2. How *Targin®* tablet works
3. Before you use *Targin®* tablet
4. How to use *Targin®* tablet
5. While you are using it
6. Side effects
7. Storage and Disposal of *Targin®* tablet
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What *Targin®* tablet is used for

Targin® tablet is used to relieve moderate to severe chronic pain when other forms of treatment have not been effective and to bring relief from constipation which is a typical side effect of treatment with opioid analgesics.

Targin® tablets are also used to relieve the symptoms of severe to very severe restless legs syndrome in people who can't be treated with dopamine medicines.

How *Targin®* tablet works

Targin® tablet contains two different medicines called oxycodone hydrochloride and naloxone hydrochloride. Oxycodone belongs to a group of medicines called opioid analgesics, which are strong pain killers and is responsible for the pain-killing effect of the tablets. Naloxone is intended to bring relief from constipation. Constipation is a typical side effect of treatment with strong painkillers

Before you use *Targin®* tablet

- When you must not use it

- Do not take *Targin®* tablets if you are allergic to oxycodone, naloxone, opioid painkillers, or any of the ingredients listed at the end of this leaflet.
- Do not take *Targin®* tablets if you
 - have any breathing problems such as severe asthma, respiratory depression (breathing slows or weakens) or other obstructive airways disease.
 - are severely drowsy or have a reduced level of consciousness
 - have heart problems due to long term lung disease (Cor pulmonale).
 - have a condition where your stomach empties more slowly than it should or any condition that obstructs the

stomach/bowel or affects bowel transit (movement of food or ingested material along the bowel).

- have moderate to severe liver problems.
- have irregular heartbeats or changes in the way the heart beats.
- have severe central nervous system depression.
- have a head injury, brain tumour or have raised pressure within the head, brain or spinal cord.
- Suffer from uncontrolled convulsions, fits or seizures.
- Suspected surgical abdomen.
- have just consumed and/or regularly large amounts of alcohol or have confusion and shaking due to alcohol withdrawal.
- take a medicine for depression called a 'monoamine oxidase inhibitor' or have taken any in the last two weeks.

Pregnancy and lactation

Ask your doctor or pharmacist for advice before taking any medicine.

Use of these tablets during pregnancy should be avoided unless your doctor thinks treatment with this medicine is essential. If used over prolonged periods during pregnancy, oxycodone may lead to withdrawal symptoms in the newborn baby. If oxycodone is given during childbirth, the baby may have breathing problems (respiratory depression). Do not take *Targin®* if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

Before treatment with these tablets tell your doctor or pharmacist if you:

- have a type of bowel obstruction (paralytic ileus) caused by opioids;
- have kidney problems;
- have mild liver problems;
- have severe lung problems (i.e. reduced breathing capacity);
- have a thyroid disorder, with dryness, coldness and swelling ['puffiness'] of the skin, affecting the face and limbs (myxoedema);
- suffer from an underactive thyroid in which your thyroid gland is not producing enough hormones (hypothyroidism);

- suffer from a condition in which your adrenal glands are not producing enough hormones (adrenal insufficiency or Addison's disease);
- have a mental disorder as a result of an intoxication (toxic psychosis);
- suffer from gallstone problems;
- have problems with your circulation;
- suffer from an abnormally enlarged prostate gland (prostate hypertrophy);
- are or ever have been addicted to alcohol or drugs, or have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating upon stopping alcohol or drugs;
- suffer from a condition in which your pancreas is inflamed (pancreatitis);
- have low blood pressure (hypotension);
- have high blood pressure (hypertension);
- have heart problems;
- have a head injury (due to the risk of increased brain pressure);
- suffer from epilepsy or are prone to fits;
- increased sensitivity to pain (Hyperalgesia)
- are galactose intolerance, lactose deficiency or glucose-galactose malabsorption.
- have inflammatory bowel disease.
- are about to have an operation or have had an operation within the last 24 hours.
- have some cancers of the digestive tract or pelvis.

Tell your doctor if you have used an opioid before.

Using *Targin®* tablets after using higher doses of other opioids may lead to withdrawal symptoms or diarrhea. These tablets should be avoided in patients with a history of, or present drug abuse and should be used with caution in elderly or weak (infirm) patients.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Some medicines and *Targin®* prolonged release tablets may interfere with each other when taken at the same time.

Targin® Prolonged Release Tablet

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These include:

- pain relievers including other strong painkillers (opioids);
- medicines used to help you sleep (sedatives) and tranquillisers (hypnotics);
- medicines used to treat depression, psychiatric or mental disorders (antidepressants);
- medicines used to treat allergies, travel sickness or nausea (anti-histamines or anti-emetics eg. metoclopramide);
- other medicines which act on the nervous system (phenothiazines, neuroleptics);
- medicines used to thin the blood (coumarin derivatives eg. warfarin);
- alcohol;
- medicines known as a MAO inhibitor (used to treat depression or Parkinson's disease).
- Taking *Targin®* with a benzodiazepine (medicine used as sedatives or to treat anxiety) can depress your central nervous system. Inform your doctor if you are currently taking any benzodiazepines.
- Seek medical attention immediately if you or the person taking this medication experience(s) symptoms of unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness.

How to use *Targin®* tablet

- How much to use

Always take these tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Swallow your tablets whole with a glass of water. You can take these tablets with or without food. Take them every 12 hours. For instance, if you take a tablet at 8 o'clock in the morning, you should take your next tablet at 8 o'clock in the evening.

Do not break, chew or crush the tablets.

Adults

The usual starting dose is 10 mg oxycodone hydrochloride / 5 mg naloxone hydrochloride every 12 hours. Your doctor will decide how much you should take every day and how to divide your total daily dose into morning and evening doses. Your doctor will also decide on any necessary dose adjustments

during treatment depending on your level of pain and individual sensitivity. You should be given the lowest dose needed for pain relief. If you have already been treated with opioids, your treatment with these tablets may be started at a higher dose.

The maximum daily dose is 80 mg oxycodone hydrochloride and 40 mg naloxone hydrochloride.

If you need a higher dose, your doctor may give you additional oxycodone without naloxone. The beneficial effect of naloxone on bowel movements may be affected if additional oxycodone is given without additional naloxone.

If you experience pain between doses, you may need to take an additional fast-acting painkiller. *Targin®* tablets are not suitable for this. Please talk to your doctor.

If you feel that these tablets are too strong or too weak, please talk to your doctor or pharmacist.

Liver or kidney problems

If you have kidney or mild liver problems your doctor may prescribe a lower dose. You must not take these tablets if you have moderate or severe liver problems, (see also section 'Before you start to use it').

Children and adolescents below 18 years of age

No studies have been carried out to show that these tablets work properly in children and adolescents, or are safe for them to take. They are therefore not recommended for use in patients under 18 years of age.

Elderly patients

In general, no dose adjustment is necessary for elderly patients with normal kidney and/or liver function.

- When to use it

Use as directed by your doctor or pharmacist. Take *Targin®* tablets every 12 hours. Taking them at the same time each day will have the best effect and will mean that the onset of pain is prevented. If however, you begin to experience sudden pain for a short period of time ('breakthrough pain') and you are taking your *Targin®* tablets as prescribed, contact your doctor as your dosage may have to be reviewed.

- How long to use it

Continue taking *Targin®* tablet for as long as your doctor recommends. Do not stop

taking these tablets without first speaking with your doctor. If you do not require any further treatment, your doctor will advise you how to reduce the daily dose gradually. In this way, you will avoid withdrawal symptoms, such as restlessness, bouts of sweating and muscle pain.

If you have any further questions on the use of these tablets, ask your doctor or pharmacist.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it. If you take a lower dose than the one prescribed, you may not feel any pain-killing effect.

Do not take a double dose to make up for a forgotten tablet.

- If you use too much (overdose)

If you have taken more than the prescribed dose, you must inform your doctor immediately.

An overdose may result in a reduction in size of pupils in the eye, breathing more slowly or weakly than expected (respiratory depression), drowsiness or loss of consciousness, low muscle tone, reduced pulse rate and a fall in blood pressure.

In severe cases, loss of consciousness (coma), fluid on the lungs (non-cardiogenic pulmonary oedema) and circulatory collapse may occur, which may be fatal.

While you are using it

- Things you must do

- Take *Targin®* tablets exactly as your doctor has prescribed.
- Before you start on a new medicine, remind your doctor and pharmacist that you are taking *Targin®* tablets.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.
- It may affect other medicines used during surgery.
- If you become pregnant while taking this medicine, tell your doctor immediately.
- Keep all of your doctor's appointments so that your progress can be checked.
- Tell your doctor if your pain is getting worse or you are having more frequent

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- sudden pain for a short period of time. Also tell your doctor if you are having any problems or difficulties while you are being treated with *Targin®* tablets.
- Tolerance to oxycodone may develop which means that the effect of the medicine may decrease. If this happens, your doctor may increase the dose so that you get adequate pain relief.
 - Keep enough *Targin®* tablets with you to last over weekends and holidays.

-Things you must not do

- Do not drink alcohol while you are taking *Targin®* tablets.
- Do not take *Targin®* tablets to treat any other complaint unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine, take more tablets than recommended by your doctor or change the dosage without checking with your doctor.
- Over time your body may become used to you taking oxycodone so if you stop taking it suddenly, your pain may worsen and you may have unwanted side effects such as withdrawal symptoms. This is called physical dependence.
- If you need to stop taking this medicine, your doctor will gradually reduce the amount you take each day, if possible, before stopping the medicine completely.

- Things to be careful of

Do not drive or operate machinery until you know how *Targin®* tablets affect you. *Targin®* tablets may cause drowsiness, dizziness, hallucinations, disorientation, blurred vision or other vision problems or may affect alertness. This is most likely at the start of your treatment after a dose increase or after switching from a different medication. These side effects should disappear once you are on a stable dose. Discuss these aspects and any impact on your driving or operating machinery with your doctor. Be careful if you are elderly, unwell or taking other medicines. Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

Tell your doctor if you suffer from nausea or vomiting when taking *Targin®* tablets. If you vomit after your dose, your pain may come back, as you may not have absorbed your medicine. If this happens, speak to your doctor. Your doctor may prescribe some medicine to help you stop vomiting.

the whole tablet in your stool. The active substances have already been released in the stomach and gut, and absorbed into your body.

There is potential for abuse of oxycodone and the development of addiction to oxycodone. It is important that you discuss this issue with your doctor.

Serotonin syndrome: *Targin®* may cause a rare but potentially life-threatening condition resulting from concomitant administration serotonergic drugs. If you have some or all of these symptoms: feeling confused, feeling restless, sweating, shaking, shivering, hallucinations, sudden jerks in your muscles or a fast heartbeat, seek medical attention immediately.

Adrenal insufficiency: Long-term use of *Targin®* may cause adrenal insufficiency, a potential life-threatening condition that may be present with a non-specific symptoms and signs such as nausea, vomiting, decreased appetite, fatigue, weakness, dizziness, and low blood pressure. Seek medical attention if you experience a constellation of these symptoms.

Infertility: Long-term use of *Targin®* may cause reduced fertility. It is not known whether these effects on fertility are reversible.

Side effects

Like all medicines, *Targin®* tablet can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Other side effects not listed below may also occur in some people.

The most serious side effect is a condition where you breathe more slowly or weakly than expected (respiratory depression). It mostly occurs in elderly and weak patients. Opioids can also cause a severe drop in blood pressure in susceptible patients.

Other important side effects are:

Common

- decreased appetite or loss of appetite
- restlessness
- a feeling of dizziness or ‘spinning’
- fall in blood pressure
- abdominal pain
- constipation
- diarrhoea
- dry mouth
- thirst
- indigestion
- vomiting or nauseous
- wind
- changes in the results of blood tests that show how well your liver is working
- rash/ skin reactions
- withdrawal symptoms such as agitation, anxiety, shaking or sweating
- feeling hot and cold
- chills
- altered mood and personality changes (e.g. depression, a feeling of extreme happiness), decreased or increased activity, agitation
- feeling anxious or nervous, trouble sleeping or abnormal dreams
- hiccups
- difficulty in passing urine
- breathing problems, such as breathing more slowly or weakly than expected (respiratory depression)
- reduction in size of the pupils in the eye
- muscle cramps and decreased cough reflex.

The active ingredient oxycodone hydrochloride, if not combined with naloxone hydrochloride, is known to have the following differing side effect:

Common

- Gastric
- Hiccup
- Drug withdrawal syndrome
- Fever
- Faintness
- Agitation and mood changes
- Renal and urinary disorder
- Bronchospasm
- Pharyngitis
- Voice alteration
- Orthostatic hypotension

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-

Targin® Prolonged Release Tablet

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78835550, or visiting the website portal.bpfk.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Targin® tablet

- Storage

Keep out of the reach and sight of children. Accidental overdose by a child is dangerous and may be fatal. Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Targin® tablets are available as oblong, film coated tablets as follow:

Targin® Tablets 5 mg/2.5 mg (blue, marked “OXN” on one side and “5” on the other)

Targin® Tablets 10 mg/5 mg (white, marked “OXN” on one side and “10” on the other)

Targin® Tablets 20 mg/10 mg (pink, marked “OXN” on one side and “20” on the other)

Targin® Tablets 40 mg/20 mg (yellow film-coated tablets, marked “OXN” on one side and “40” on the other)

Aluminium/ aluminium foil blisters containing 14 tablets per blister. Each carton contains 2 blisters; a total of 28 tablets per carton.

- Ingredients

Active ingredients:

Targin® Tablet 5 mg/2.5 mg (5 mg of oxycodone hydrochloride / 2.5 mg naloxone hydrochloride)

Targin® Tablets 10 mg/5 mg (10 mg of oxycodone hydrochloride / 5 mg naloxone hydrochloride)

Targin® Tablet 20 mg/10 mg (20 mg of oxycodone hydrochloride equivalent / 10 mg naloxone hydrochloride)

Targin® Tablets 40 mg/20 mg (40 mg of oxycodone hydrochloride / 20 mg naloxone hydrochloride)

Targin® tablet contains lactose anhydrous.

Inactive ingredients:

- Ethylcellulose,
- Stearyl alcohol,

- Lactose monohydrate,
- Talc,
- Magnesium stearate.
- Poly(vinylalcohol),
- Titanium dioxide (E171),
- Macrogol 3350,
- Talc.

Targin® Tablets 5 mg/2.5 mg contains Hydroxypropylcellulose.

Targin® Tablets 10 mg/5 mg, 20 mg/10 mg, 40 mg/20 mg contains Povidone K30. The colouring agents used for the tablets are as follows:

Targin® Tablets 5 mg/2.5 mg contains Brilliant Blue FCF aluminium lake (E133)

Targin® Tablets 20 mg/10 mg contains Iron oxide red (E172)

Targin® Tablets 40 mg/20 mg contains Iron oxide yellow (E172)

MAL numbers:

Targin® Tablets 5mg / 2.5mg – MAL12055007ACRZ

Targin® Tablets 10mg / 5mg – MAL12055001ACRZ

Targin® Tablets 20mg / 10mg – MAL12055006ACRZ

Targin® Tablets 40mg / 20mg – MAL12055011ACRZ

Manufacturer

Bard Pharmaceuticals Limited Cambridge Science Park Milton Road, Cambridge Cambridgeshire CB4 0GW, UK

Product Registration Holder

DKSH MALAYSIA SDN BHD B-11-01, The Ascent, Paradigm, No. 1, Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor, Malaysia.

Date of revision

14/03/2024 (based on Targin® PI 30 Nov 2017 CCDSv09)

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